

## **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-3, 5, 7, 11, 13, 15, 17, and 19-41, 101, and 104-107 are currently under consideration. Claims 19-27, 101, 106 have been amended, and claims 9, 102, and 103 have been canceled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

### **II. OBJECTIONS TO THE CLAIMS ARE OVERCOME**

Claims 19-39 have been objected to for being dependent in part on canceled claim 4. By this paper, claims 19-27 have been amended to eliminate the reference to claim 4. Accordingly, reconsideration and withdrawal of the objection to the claims are respectfully requested.

Claim 9 has been objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5. By this paper, claim 9 is hereby cancelled. Accordingly, reconsideration and withdrawal of the objection to the claim are respectfully requested.

### **III. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH ARE OVERCOME**

Claims 101-107 have been rejected under 35 U.S.C., first paragraph, as failing to comply with the written description requirement. The Office Action alleges that the reference to a "first support hook" in claim 101 does not comply with the description, as the description "fails to

provide adequate support for a 'first' hook as only one support hook has been described." In response, the Applicant has amended claims 101 and 106 to recite "a support hook" rather than a "first support hook." Moreover, claim 101 has also been amended to recite "a means for hanging an outlet storage container" rather than "a second support hook for attachment of an outlet storage container." Support for these amendments is on page 23, lines 19-23. Accordingly, reconsideration and withdrawal of the rejection to the claims are respectfully requested.

The Office Action contends that claims 101-107 are not enabled by the specification to teach a device for treating a "starting cell population which is any other cellular population" other than blood. To address this rejection, the Applicant has amended claim 101 to specify "starting hematopoietic cell population." Support for this amendment is on page 6, line 23 to page 7, line 3, and page 13, line 19.

The Office Action asserts that claims 101-107 are not enabled by the specification to encompass a device that comprises an inlet storage container containing a starting cell population other than blood, and that the only recited means for using the device is for the "single recited means of a blood bag as input into the device." In response, the Applicant has amended claim 101 to cite "wherein said inlet storage container is a blood bag" and "wherein said outlet storage container is a blood bag. Support for these amendments is on page 22, lines 21-25 and lines 27-31, page 23, lines 19-23, and page 23, line 28 - page 24, line 18. Furthermore, claims 102 and 103 have been canceled. Accordingly, reconsideration and withdrawal of the rejection to the claims are respectfully requested.

#### **IV. THE REJECTIONS UNDER 35 U.S.C. §103(a) ARE OVERCOME**

Claims 1-3, 15, 17, and 19-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gruenberg (U.S. Patent No. 5,627,070) in view of Glockner et al. (WO 00/53797) and Milande et al. (WO 99/28438). The rejection is respectfully traversed.

The Office Action states that Gruenberg mentions a cell growing device using capillaries that allow media to permeate across to cells located in the extracapillary space. The device also includes a gas delivery mechanism and a monitoring mechanism for observing gas and pH levels. Glockner et al. (hereinafter "Glockner"), according to the abstract, refers to a method for in vitro testing active ingredients in cells, which involves a designed cell culture dish and a means for introducing at least one active ingredient to the cells. Milande et al. (hereinafter

“Milande”), according to the abstract, mentions a device for the cell culture of hematopoietic cells that is comprised of a cell cultivation chamber with gas-permeable capillaries and a means for variable delivery of media. The Office Action asserts that Milande “provides a device in which a mixing means can be implemented” and that it would have been “prima facie obvious at the time the claimed invention was made to provide a magnetic stirrer as a means for distributing a homogenous concentration of a test agent onto the cells in culture.” The Office Action contends that one skilled in the art would have been motivated to include the magnetic stirrer “by the general knowledge in the art that experimental variations will result from the use of a solution which is not homogenous.” The Applicant respectfully disagrees.

It is respectfully submitted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further still, “obvious to try” is not the standard under 35 U.S.C. § 103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure.** *In re Dow*, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988).

Regarding the references cited in the Office Action, Gruenberg, Glockner, and Milande, combined or individually, do not teach any means for mixing an agent and a cell population, nor do they suggest that such a mixing means is necessary. Furthermore, in contrast to the statements in the Office Action, the abstract of Milande exhibits no indication that suggests a mixing means can be implemented. According to the diagram in the abstract of Milande, the cell cultivation chamber features tubes that are dispersed between the micronic screens, and is not conducive to using a magnetic stirrer as suggested in the Office Action. As such, there is not a reasonable expectation that a mixing means can be successfully implemented into the device. Therefore, the combination of Gruenberg, Glockner, and Milande do not suggest all of the claim limitations, as none of these references suggest or teach a means to mix an agent and a cell

population. Accordingly, reconsideration and withdrawal of the rejection to the claims are respectfully requested.

Claims 1-3, 5, 7, 9, 15, 17, and 19-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gruenberg, Glockner, and Milande as applied to claims 1-3, 15, 17, and 19-41, and further in view of Von Behrens et al. (WO 93/16384). The rejection is respectfully traversed.

The Office Action states that Von Behrens et al. (hereinafter “Von Behrens”) refers to a method of counting cells in a sample solution by measuring electrical impedance across an orifice through which the sample solution is caused to flow. The Office Action contends that it would have been prima facie obvious “to include devices for cell counting by means of cytometer or Coulter counting as part of the automated tissue culture device.” To reiterate the previous traversal described above, Gruenberg, Glockner, and Milande do not teach all of the elements of the presently claimed invention, as none of these references suggest or teach a means to mix an agent and a cell population. The teaching of Von Behrens does not remedy this deficiency. Thus, the combination of Gruenberg, Glockner, Milande, and Von Behrens does not render this present invention as obvious and, accordingly, reconsideration and withdrawal of the rejection to the claims are respectfully requested.

Claims 1-3, 11, 13, 15, 17, and 19-41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gruenberg, Glockner, and Milande as applied to claims 1-3, 15, 17, and 19-41, and further in view of Hochman. (U.S. 5,976,825). The rejection is respectfully traversed.

The Office Action states that Hochman alludes to methods for screening candidate drugs for activity to prevent or inhibit Alzheimer’s disease or CNS-based swelling and uses a host computer system to control mechanical interfaces such as motor driven syringes. The Office Action contends that it would have been prima facie obvious “to incorporate a motor driven syringe into the device” in order to “introduce relatively small amounts of serum, growth factors, and hormones into the cell culture medium as needed.” Again, as described in the traversal above, Gruenberg, Glockner, and Milande do not teach all of the elements of the presently claimed invention, as none of these references suggest or teach a means to mix an agent and a cell population. The teaching of Hochman does not remedy this deficiency. Thus, the combination of Gruenberg, Glockner, Milande, and Hochman does not render this present

invention as obvious and, accordingly, reconsideration and withdrawal of the rejection to the claims are respectfully requested.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

### **CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

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